MAR 2 2 2005

K043315

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Heather Crawford, RAC
Director of Regulatory Affairs
863-683-8680 [voice]
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hcrawford@safe-reuse.com [email]

Date

November 24, 2004

Device

- Trade Name: Vanguard Reprocessed Hand-Activated Ultrasonic Scalpel
- Common Name: Ultrasonic Surgical Instrument
- 21 CFR Section: Unclassified
- Reprocessed – Class II
- Product Code: NLQ

Predicate Devices

- Trade Names:
  - Ethicon Endo-Surgery UltraCision® Harmonic Scalpel®
- 510(k) numbers:
  - K925699: Ultracision, Inc., Harmonic Scalpel Laparosonic Clamp Coagulator
  - K980099: Ethicon Endo-Surgery, Inc., UltraCision LaparoSonic Coagulating Shears LCS-5
  - K993054: Ethicon Endo-Surgery, Inc., UltraCision Harmonic Scalpel LCS and CS Curved Shears

Indications for Use

The Reprocessed Hand-Activated Ultrasonic Scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

Contra-indications

This instrument is not intended for contraceptive tubal ligation or for bone excision.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

The Reprocessed Hand-Activated Ultrasonic Scalpels are hand held instruments which may be used to cut and coagulate tissue when connected to a compatible ultrasonic handpiece and generator. Scalpels are 5mm in diameter with a functional length of 36cm. The instrument jaws are opened and closed using proximal ring handles, styled in a pistol-type grip. The instrument tip and shaft can be rotated 360° in either direction using a knob on the handle. The Scalpel has a curved active blade.

The proximal handle is designed for attachment to a compatible handpiece and microprocessor controller. Electrical outputs from the controller are converted by an ultrasonic transducer within the handpiece to mechanical vibrations that are transmitted through the instrument shaft to the distal scalpel blade. The proximal handle of the Hand-Activated Ultrasonic Scalpel has two integrated push buttons that allow hand control of the ultrasonic power level (minimum or maximum power level).

Vanguard receives previously used Ultrasonic Scalpels from healthcare facilities; cleans, inspects, tests, packages, labels, and sterilizes the devices; and returns them to a healthcare facility for subsequent use.

Technological Characteristics

The Vanguard Reprocessed Hand-Activated Ultrasonic Scalpels are essentially identical to the currently marketed Original Equipment Manufacturer (OEM) devices. Device materials, specifications, and technological characteristics are equivalent.

Test Data

Cleaning, sterilization, and packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Ultrasonic Scalpels are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2006

Ascent Healthcare Solutions
% Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, Arizona 85044

Re: K043315 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Name: Ultrasonic Surgical Instrument
Regulatory Class: Unclassified
Product Code: NLQ
Dated: February 24, 2005
Received: February 25, 2005

Dear Ms. Barton:

This letter corrects our substantially equivalent letter of March 22, 2005. The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on March 22, 2005. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the device listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043315

Device Name: Vanguard Reprocessed Hand-Activated Ultrasonic Scalpel

Indications For Use:

Reprocessed Hand-Activated Ultrasonic Scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043315

List of Models:

Ethicon LCSB5HA 5mm Coagulating Shears, Pistol Grip with Integrated Push Buttons, 36mm, Curved Active Blade